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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,715	07/20/2001	Brian J. Cox	18455.11	1492

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	22

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,715	COX, BRIAN J.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-86* is/are pending in the application.

4a) Of the above claim(s) *59,70-75,78-80 and 86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-58, 60-69, 76, 77, 81-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-2-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 59, 70-75, 78-80, and 86 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These claims are directed to subject matter (non-cylindrical support member, vascular patch device, coiled bridge device, bifurcated vascular support device, an expandable intra-aneurysmal bridge device, and a device within an aneurysm).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively *elected by original presentation* for prosecution on the merits. Accordingly, claims 59, 70-75, 78-80, and 86 are *withdrawn from consideration* as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

2. The disclosure is objected to because of the following informalities: In the Abstract, in lines 4-5, the phrase "The body member provide support mechanical support..." should be revised, as it is incorrect grammatically.

Appropriate correction is required.

Claim Objections

3. Claim 50 is objected to because of the following informalities: "therpeutic" is spelled incorrectly. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was *not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention*. The specification does not describe a *how* a reactive material that appears to be applied uniformly to the outer surface of support member (24) would expand more in one direction than another. Nowhere in the specification is the *chemistry*, which causes this hydrogel to expand in such an anisotropic manner.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 44-49, 51-56, 60-69, 76, 77, 81-85 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,769,882 to Fogerty et al. Regarding Claims 44 and 77, Fogerty discloses the invention as claimed. Fogerty discloses an apparatus—"stent" [Column 5, lines 23-25]—for treating vascular aneurysms including a support member (10/22), which is radially and axially *reticulated* expanding stent with a cylindrical body [see Figure 4]. It has an internal lumen and many fenestrations

(openings) because of its lattice shape, *as is well known in the art*, and *specifically disclosed in Column 5, lines 52-57*. The stent is expandable [Column 5, lines 38-51], and therefore in its unexpanded state will have a diameter D, and in its expanded state will have a diameter D', which is larger than D. Fogerty is very specific in that section about the precise dimensions of the expanded and unexpanded diameters. The tubular support member (10/22) has a reactive material "sealing layer 14" [see Fig. 4], which is capable of restricting blood flow to the aneurysm [Column 6, lines 33-45]. Figure 4 shows the reactive material (14) blocking the blood, preventing it from entering the aneurysm (A). The reactive material is applied at a certain (particular) location on the fenestrated stent.

6. Regarding Claim 45, Fogerty's reactive material can be polymer [Column 6 line 66 to Column 7 line 1].

7. Regarding Claims 46-48, Fogerty's reactive material, in fact, is a hydrogel [Column 7, lines 6-25] and has an unswelled (non-reacted state) state and a reacted state, when it is swelled [Column 7, lines 22-32]. Because Fogerty's reactive material (14) is a hydrogel, just like the Applicant's, it will react in the same ways to the blood (including the pH of the blood), and other internal fluids and proteins of the vasculature.

8. Regarding Claim 49, Fogerty discloses using the stent to deliver a therapeutic agent such as a drug [Column 6, lines 12 and 13]. He also discloses coating the stent with a laminant [Column 6, lines 26-28], which would aid in the therapeutic use of the stent.

9. Regarding Claims 51 and 52, Figure 4 shows the reactive material (14) blocking the blood, preventing it from entering the aneurysm (A). The reactive material is applied at a certain (particular) location on the fenestrated stent. The stent has many surfaces, because it is composed of various fibers. The reactive material will touch various parts of different surfaces.

Further, the stent (10) has an exterior surface. That exterior surface can be considered to have a left part and a right part. The reactive material (24) is shown covering both the left exterior surface and the right exterior surface in Fig. 8. One embodiment of Fogerty's invention is of the reactive material (24) covering the whole exterior of the graft (both the left exterior surface and the right exterior surface) [Column 6, lines 38-42]. The Applicant has not made any particular limitations on where the surfaces are or what they look like.

10. Regarding Claim 53, the Applicant is directed to Column 7, lines 33-43. There, Fogerty discloses a cuff, which can be considered to be a further extension of the support member. He says that the cuff is placed on the outside of the tubular member (10/22) and that that cuff can be partially made out of PTFE and partially out of a hydrogel [Column 7, lines 39-41]. In that instance, the hydrogel can be considered to be support member, as it is forming a part of the cuff that is a solid component, which (along with the tubular member) supports the interior wall of the vessel/aneurysm.

11. Regarding Claim 54, similarly to the above paragraph, the hydrogel, which forms part of the cuff, can be considered to be integrally formed with the other support members made up of PTFE. That is, the cuff consists of PTFE and hydrogel—the

hydrogel support members are next to the PTFE support members of the fabric. The two are formed together, as one piece.

12. Regarding Claim 55, the reactive material of Fogerty's invention has a non-reactive volume of V and a reacted volume of V', wherein V' is larger than V. In Column 7, lines 3-7, Fogerty explains that the reactive material (14) may be a hydrophilic gel that absorbs body fluids to go from an assumedly smaller volume of V to a swelled, fluid-holding state with a volume of V'.

13. Regarding Claims 56, 82, and 83, the reactive material is capable of obtaining a reacted volume V' in the presence of a physiological pH of about 7.4. *The normal pH of blood is between 7.35 and 7.45* [MedicineNet.com article], and because Fogerty's invention is meant to be applied to the inside of blood vessels, the reaction (swelling) will occur at a pH of about 7.4.

14. Regarding Claims 60, 84, and 85, Fogerty's support member (10/22) is delivered to a site in a living body, using a balloon catheter and a guidewire [Column 9, lines 5-37].

15. Regarding Claim 61, a balloon catheter is a mechanical means of delivering the support member (10/22).

16. Regarding Claims 62 and 63, the support member contains an attachment device, such as adhesive [Column 6, lines 46-57]. Additionally, as also described in that passage, the reactive material (10) itself may serve as an anchoring device, disallowing the stent to move downstream of the aneurysm.

17. Regarding Claim 64, the support member is manufactured from the shape memory alloy, Nitinol [Column 6, lines 29-32].

18. Regarding Claim 65, the material comprising the support member may be radio-opaque [Column 6, lines 7-14].

19. Regarding Claim 66, Fogerty's support member can be made out of all of the materials disclosed as the applicant's support member, and will therefore have the same properties as the Applicant's. For that reason, although not specifically disclosed as "echo-genic," Fogerty's support member will have internal echoes, just like the Applicant's.

20. Regarding Claim 67, Fogerty's stent fits inside a blood vessel in its expanded state [see Fig. 4].

21. Regarding Claims 68 and 76, Fogerty's stent has helically shaped fibers [Column 6, lines 20-22].

22. Regarding Claim 69, the cuff discussed above is a fabric and fabrics are made through weaving. Fogerty explains that the cuff *itself* is absorbable (Column 7, lines 33-34, and afterwards, that the cuff is made by weaving or knitting. Extrapolating, because he says, "the hydrogel can be placed inside the water permeable membrane," (lines 39-40) the hydrogel must be knitted into the PTFE fabric of the cuff.

Further, in Column 11 lines 3-8, Fogerty explains that his reactive material (14) may be formed into an unsupported *woven fabric*. In light of Fogerty's specification, an unsupported woven fabric implies that the fabric is made out of both hydrogel and another more hearty, strong material.

23. Regarding Claim 81, Fogerty discloses the method, as claimed, and as explained with reference to Claims 44 and 77 above. Fogerty's structure allows blood to flow through a blood vessel. Also, Fogerty's method includes activating a reactive material disposed on a *certain part of* his device to restrict blood flow to an aneurysm [Column 6, lines 33-45]. One of the important ways in which Fogerty's reactive material (14) reacts within the body is to swell in the presence of a liquid such as blood.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

24. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,769,882 to Fogerty et al in view of U.S. Patent No. 5,609,629 to Fearnot et al. Fogerty does not disclose coating his stent with specific drugs, but Fearnot teaches applying anti-restinosis drugs to a stent in order to prevent the vessel from clotting/closing again after the application of a stent [Column 7, lines 30-47]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply an anti-restinotic compound to a stent, as taught by Fearnot, in order to maintain patency of the inner lumen of a blood vessel after the application of a stent.

25. Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,769,882 to Fogerty et al in view of U.S. Patent No. 6,264,695 B1 to Stoy. Fogerty discloses a stent having uniformly expanding hydrogel applied to its

surfaces [see above]. Stoy teaches that a hydrogel applied to a medical implant should swell "anisotropically"—more in the axial direction than in the radial direction [Column 12, lines 11-38] because excessive expansion in the radial direction can have unnecessary deleterious effects on the internal body tissues [Column 13, lines 21-26].

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,674,295 to Ray et al.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Milano
Supervisory Patent Examiner
Art Unit 3731

BCP
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March 24, 2004